16 15
~~39~~. The composition of claim ~~38~~, wherein: R_1 = H, C_1-C_{12} straight chain or branched alkyl, or cationic salt moiety; and R_2 and R_3 taken together represent O.

17 16
~~40~~. The composition of claim ~~39~~, wherein the compound of formula (IV) is selected from the group consisting of 3-oxacloprostenol, 13,14-dihydrofluprostenol, and their pharmaceutically acceptable esters and salts.

18 15
~~41~~. The composition of claim ~~38~~, wherein: R_1 = H or C_1-C_{12} straight chain or branched acyl; and R_2 = R_3 = H.

19 18
~~42~~. The composition of claim ~~41~~, wherein the compound of formula (IV) is dihydrocloprostenol pivaloate.

20 12
~~43~~. The composition of claim ~~35~~, wherein the concentration of the compound of formula (IV) is between about 0.0003 and about 0.3 wt%.

21 20
~~44~~. The composition of claim ~~43~~, wherein the concentration of the compound of formula (IV) is between about 0.0003 and about 0.3 wt%.

22 21
~~45~~. The composition of claim ~~44~~, wherein the concentration of the compound of formula (IV) is between about 0.003 and about 0.03 wt%.

REMARKS

This application is a Rule 60 continuation of U.S. Patent Application Serial No. 08/769,293, expected to issue shortly as U.S. Patent No. 5,665,773 (the "Parent Application"), which is a file wrapper continuation of U.S. Patent Application Serial No. 08/280,681, now abandoned, which was a continuation-in-part of U.S. Patent

36

Application Serial No. 08/101,598, now U.S. Patent No. 5,510,383. In addition to updating this patent history, the present Amendment cancels the pending claims for the present application and replaces them with new claims 24-45. As will be explained in more detail below, the new claims generally correspond to the allowed claims of the Parent Application, but are directed to compositions comprising specific isomers of the compounds, and being substantially free of the enantiomers thereof.

Claim 24, added by the present amendment, corresponds to allowed claim 1 of the Parent Application. The Examiner will note that there are two differences between newly added claim 24 and claim 1 of the Parent Application. First, whereas the independent claim of the Parent Application is directed to a method comprising the topical administration of a compound of formula IV, the method of claim 24 comprises administering a "composition comprising a therapeutically effective amount of a compound having the absolute stereochemical structure of the following formula (IV), and being substantially free of the enantiomer of said compound..." (emphasis added). Those skilled in the art will appreciate that the compounds of formula (IV) are all chiral compounds. Each such compound will have two enantiomers, that have the same relative configuration, but are mirror images of each other. All of the presently added claims are directed to compounds having the absolute stereochemical structure defined by formula (IV) in a composition that is substantially free of the mirror-image compound, i.e. the enantiomer. Support for this amendment is found in the specification in Table I and Examples 1-4 at pages 7-23. Each of the synthetic examples (1-4), describe chiral syntheses of the desired compounds. That is to say that the yield of each such synthesis would be an enantiomerically pure compound which, by definition, would be substantially free of its enantiomer. Because the syntheses described in Examples 1-4 are "representative in nature" (page 6, line 7), they support the "absolute stereochemical" limitation for all of the compounds of formula (IV). Consequently, the applicants respectfully submit that the claim limitations added by the present

amendment are fully support by the specification and do not constitute the addition of new matter.

The second difference the Examiner will note between the presently amended claim 24 and claim 1 of the allowed parent application lies in the "proviso" excluding certain compounds from the scope of the claim. Excluded from the scope of the independent claim in the parent application were cloprostenol, fluprostenol and their analogs, which had been claimed in an earlier application (U.S. Application Serial No. 08/101,598, now U.S. Patent No. 5,510,383). Because none of the claims of that prior application contain limitations requiring that the compound be enantiomerically pure, it is not necessary to exclude those compounds from the presently amended claims. Support for the amendment is found at pages 3 and 4 of the specification where the description of the compounds of formula (IV) does not exclude cloprostenol, fluprostenol and their analogs. Applicants respectfully submit, therefore, that this component of the present amendment is also supported by the specification, adds no new matter, and creates no obviousness-type double patenting problem relative to any of the prior applications.

Newly added claims 25 and 26 depend from claim 24 and are limited to cloprostenol, fluprostenol and their analogs. Cloprostenol and fluprostenol are disclosed in the specification at pages 1 and 2, as structures II and III, respectively.

Added claims 27-34 track allowed claims 2-9 of the Parent Application.

Added claims 35-45 are ophthalmic composition claims that correspond generally to the allowed composition claims of the Parent Application. Thus, independent claim 35 corresponds to allowed claim 10 of the Parent Application with the two differences discussed above relative to added claim 24. Claims 36 and 37 correspond to the added method claims 25 and 26 covering cloprostenol,

fluprostenol and their analogs. Claims 38-45 track allowed claims 11-18 of the Parent Application. There are no claims added by the present amendment which correspond to allowed claims 19 and 20 of the Parent Application. For the reasons set forth above concerning the added method claims, the applicants respectfully submit that the ophthalmic composition claims added by the present amendment are supported by the specification, add no new matter, and create no obviousness-type double patenting problem relative to prior applications.

The applicants consider the amended claims to be in condition for allowance, and respectfully request the Examiner's favorable consideration.

Respectfully submitted,

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Date: 8-21-97

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